Exhibit 16

United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al.,
Civil Action No. 05-11084-PBS

Exhibit to the Memorandum In Support of United States' Motion To Exclude Certain Opinions of W. David Bradford, PH.D

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

SUBJECT: Arkansas Department of Human Services
Docket No. 90-119
Decision No. 1273

DATE: August 22, 1991

DECISION

The Arkansas Department of Human Services (State) appealed a determination by the Health Care Financing Administration (HCFA) disallowing federal financial participation (FFP) claimed by Arkansas under Title XIX of the Social Security Act (Act) for drugs provided to Medicaid recipients from April 1 through July 31, 1989. The State had paid for the drugs based on use of the "average wholesale price" (AWP) plus the dispensing fee established by the Medicaid State Plan in effect during the disallowance period ($4.01). During Board proceedings, HCFA agreed to reduce the disallowance amount to $589,382. Essentially, HCFA's current position is that the AWP minus 10.5% of the AWP, plus the $4.01 dispensing fee, acts as an aggregate limit on the drug payments.

The State first argued that application of the AWP minus 10.5% to the period in question here was reasonable only if the increased dispensing fee adopted in a later amendment to the State Medicaid Plan is also applied. When HCFA responded that it was required to apply the $4.01 dispensing fee, the State asserted, as it had previously, that the AWP represented the State's "best estimate of the price generally and currently paid for those drugs," as required by the Medicaid regulations. The State requested, and received, an opportunity for an evidentiary hearing to provide testimony the State said would show that the AWP constituted its "best estimate" during the disallowance period.

For the reasons stated below, we conclude that the State could not reasonably consider the AWP to be its "best estimate" since the State was aware that pharmacists

generally paid less than that amount and since the State had no pertinent records to support a determination that the AWP represented the price generally and currently paid. We further conclude, however, that HCFA should reconsider its position on how to calculate the amount that should be disallowed as a result of the State's failure to timely develop a supportable estimate. Thus, we uphold the disallowance in principle, but remand to HCFA to reconsider the disallowance amount, in light of the factors outlined below.

I. Background

A. Requirements for drug payments

Section 1902(a)(30)(A) of the Social Security Act requires Medicaid state plans to provide methods and procedures "to assure that payments are consistent with efficiency, economy, and quality of care." Rules published in July 1987, and in effect throughout the period involved here, control payments for drugs under Medicaid. 42 C.F.R 447.331 - 447.334. For some drugs, HCFA lists specific payment limits. For unlisted drugs and certain others, all called "other drugs," a state's payments --

> . . . must not exceed in the aggregate, payment levels that the [state] agency has determined by applying the lower of the --
>
> (1) Estimated acquisition costs plus reasonable dispensing fees established by the [state] agency; or
>
> (2) Providers' usual and customary charges to the general public.

42 C.F.R. 447.331(b).

The "estimated acquisition cost" (EAC) is defined in 42 C.F.R. 447.301 as the state's "best estimate of the price generally and currently paid" by providers for a drug.

The Medicaid regulations further require each state to make findings and assurances, in its state plan, that its Medicaid expenditures for all other drugs, in the aggregate, are in accordance with 42 C.F.R. 447.331, and to maintain "data, mathematical or statistical computations, comparisons and any other pertinent records to support its findings and assurances." 42 C.F.R. 447.333.

B. Drug pricing generally

There is a history of concern in the Medicaid program about controlling costs of drugs. One problem was states' use of the "average wholesale price" (AWP) of drugs as a measure of acquisition cost. The "wholesale" element could be quite misleading, because there were sales promotions, allowances and discounts which reduced the actual prices pharmacists paid below the AWP.

In the mid-1970's, HCFA had proposed to limit payment to actual acquisition costs, apparently to counter the practice of using the AWP in national drug pricing publications. Determining actual costs was burdensome, however, and the agency ultimately decided to specify use of estimated costs in its regulations (but HCFA explained in the preamble that it was specifically rejecting the suggested use of the AWP, on the basis that it frequently produced an inflated figure). 40 Fed. Reg 34518 (1975). The estimate made by the state agency was to be consistent with "any drug price information furnished the program agency by the Department [HHS]." 45 C.F.R. 19.3(b) (1975).

An audit conducted in 1983 by the HHS Office of the Inspector General (OIG) in six states (including Arkansas) found that pharmacists' drug costs averaged about 16% below the AWP, and that in only 14 of 3,469 purchases examined did providers pay the AWP or higher (and then for extenuating reasons). HCFA Exhibit (Ex.) F, p. 4.

The current rules were adopted effective October 29, 1987; among the changes, the rules applied limits on an aggregate rather than a drug-specific basis. One purpose of this change was to give some flexibility to states to establish reimbursement methods. In discussing the requirements for findings and assurances and related recordkeeping, however, the preamble to the rule indicated that HCFA expected the states "to determine the estimated acquisition costs before making comparisons on the aggregate basis." 52 Fed. Reg. 28648, 28654 (July 31, 1987).

C. The Arkansas State Plan and proposed amendments

The Arkansas State Plan provision on drug payments which was in effect during the disallowance period (and was effective January 1, 1987) states that the State will pay the lower of the provider's usual and customary charge or

the "cost of the drug plus a $4.01 dispensing fee." HCFA Ex. A. In practice, the State was paying the AWP plus the dispensing fee (if this total was lower than the usual and customary charge).[1]

On February 11, 1988, the State submitted an amendment to its State Plan (Transmittal No. 88-05) which would have defined estimated acquisition cost to be the AWP. HCFA asked for clarifying information in a letter dated April 12, 1988, citing to various studies as evidence that "use of the AWP is not the State's best estimate . . . ." HCFA Ex. H.

In a response received June 22, 1988, the Director of the State's Division of Economic and Medical Services explained why the State considered the available information on drug prices to be outdated, inconsistent, arbitrary, and statistically incomplete. He expressed concern, however, that "AWP is an artificially high basis for reimbursement." HCFA Ex. G, p. 5. He said the State was entering into a bidding process for a pricing survey to determine the actual acquisition price and to modify the reimbursement structure accordingly. Id.

HCFA notified the State by letter dated September 20, 1988, that it was disapproving State Plan Transmittal No. 88-05, on the basis that AWP could not qualify as the State's best estimate under the regulation.[2] After

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[1] At the hearing, HCFA indicated that it was in the process of calculating a reduction in the disallowance amount to reflect the fact that the State had not paid the AWP plus dispensing fee where this total was greater than the usual and customary charge. Transcript of hearing (Tr.), p. 17. We assume that the $589,382 figure used in HCFA's post-hearing brief reflects this reduction, or, if it does not, HCFA will make this adjustment, as agreed.

[2] The State requested a hearing on the plan approval, but the administrative law judge appointed as the hearing officer stayed the case pending appeal of the related disallowance. We note that a court has held that HCFA may properly deny a Medicaid state plan amendment which proposes to set a state's EAC at AWP in the absence of a showing that AWP is in fact that state's "best estimate" of the price generally and currently paid. Louisiana v. U.S. Dept. of Health and Human Services, 905 F.2d 877 (5th Cir. 1990).

receiving this notice, the State issued an invitation for bids for a survey and, on December 3, 1988, entered into a contract with the accounting firm of Myers and Stauffer to conduct a survey of Arkansas retail drug prices and of dispensing costs incurred by pharmacies. Tr., pp. 61-62; 141-142.

HCFA advised the State, in a letter dated February 8, 1989, that, if the State had not implemented an acceptable plan amendment by April 1, 1989, HCFA would begin to defer the federal share of prescribed drug expenditures. The State responded in a letter dated February 17, 1989, informing HCFA that it had contracted with Myers and Stauffer to conduct a survey and that the State expected to receive the results by May 31, 1989 and to implement an EAC at "this time." State Ex. D.

In a letter dated March 31, 1989, HCFA stated:

> Your expenditure report for the period April 1 through June 30 is due in August and our actions at that time will depend on the actions which have been taken by the State. As pointed out in your letter, you should have the results of the survey by May 31 which is well in advance of your expenditure report due date. If you take immediate action to base your drug ingredient cost estimate on verifiable data from that survey and put an approvable methodology in place during the April-June quarter, we will not include in our review expenditures made before the date the methodology is in place.

State Ex. E.

The State encountered some delays in obtaining the survey results (discussed below), and did not receive the survey report until about June 14, 1989. Tr., pp. 69, 141-142. The report (which was 60 pages plus attachments) found that the average discount from AWP in Arkansas was 13%. HCFA Ex. B. The State sought some clarifications from Myers and Stauffer, held meetings to discuss the survey results, developed a state plan proposal and received internal approval for it, and submitted the proposal to HCFA on July 21, 1989. Tr., pp. 23, 69-74. The proposed plan amendment, Transmittal No. (TN) 89-24, would have

established the EAC at AWP minus 7% and raised the dispensing fee to $4.39 plus .095(EAC). State Ex. F.[3]

After engaging in discussions with HCFA, the State submitted a revised version of plan amendment TN 89-4, which defined the EAC as AWP minus 10.5% and set a dispensing fee of $4.16 plus .093(EAC). State Ex. H. HCFA approved the revision in July, 1990, with an effective date of August 1, 1989. State Ex. G.[4]

Meanwhile, HCFA had issued this disallowance on May 2, 1990, calculating the disallowance amount using AWP minus 13%. Based on the revised plan amendment, HCFA reduced the disallowance amount (and also settled a related disallowance for a later period).

II. The parties' arguments

The State argued that it has always been considered the role of the State to determine how it would arrive at the best estimate of the cost of the drug. The State asserted that, up until a few years ago, 20 states had used AWP. The State acknowledged that since that time there has been a move to become more accurate about the "real cost" of drugs. Tr., p. 10. The State said, however, that it had been actively engaged since 1987 in assessing what is the best estimate, but that there was no scientific study to assess the costs in Arkansas until the Myers and Stauffer study was completed in June 1989. The State argued that it was generally accepted and recognized nationwide that the AWP should be used "until such time as there was objective scientific information

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[3] The State presented testimony explaining why it had not adopted the average discount from the AWP (13%) reported in the survey report. Essentially, the State was concerned that since about 30% of the pharmacies were paying more than the average amount, these pharmacies would drop out of the program if the average discount were adopted as the EAC and that this would reduce accessibility of services. See Tr., pp. 33-35, 70; HCFA Ex. B, Appendix, p. A-67.

[4] HCFA first said that it chose this effective date because this was the date the State requested in its transmittal. When the State asked if HCFA could nonetheless make the amendment retroactive HCFA declined, apparently on the basis that the State had not implemented the amendment until August 1, 1989. See our discussion of this below.

to the contrary." Tr., p. 12. The State asserted that, once it had such information, it had acted promptly to evaluate that information, to propose a plan amendment, and to implement the proposed amendment. The State argued that it had the burden only to develop what it considered to be the best estimate and that it had met that burden.

The State also argued that it did not have notice until HCFA rejected that plan amendment specifying AWP in September 1988 that HCFA would not consider an undiscounted AWP to be consistent with the regulatory requirement. The State said that it had informed HCFA of the delays in the survey process, arguing that even with the delays, the survey was completed in less time than such surveys normally take.

HCFA argued that the State's payment of the AWP did not comply either with the regulation or with the State Plan. HCFA said that the State should have known it could not pay AWP, in light of the OIG report (which State officials acknowledged having seen) and of the statements about the AWP HCFA had made. HCFA also cited the statement in the April 12, 1988 letter from HCFA that "use of an unmodified AWP would make the amendment violate Section 1902(a)(30) of the Act and implementing regulations at 42 C.F.R. 447.200." HCFA Ex. H. HCFA argued that, although none of the various drug price surveys and pricing data were conclusive for Arkansas, "they collectively show a persuasive pattern that AWP is not the actual selling price of drugs anywhere such surveys were conducted." HCFA post-hearing brief, p. 8. HCFA argued that the State was unreasonable in delaying until September 1988 to commence a process to determine drug prices in Arkansas.

HCFA further argued that it had acted reasonably in quantifying the disallowance by applying the AWP minus 10.5% since the State had not properly quantified what price was being paid for the drugs and since the AWP minus 10.5% was the amount ultimately agreed to based on the survey data, which was from 1988.

Below, we first address the question of whether the AWP qualified as the State's "best estimate of the price generally and currently paid" during the disallowance period. We then address whether HCFA reasonably calculated the amount of unallowable costs incurred as a result of the State's use of the AWP.

III. Analysis

The key issue here is whether the AWP can reasonably be considered the State's best estimate during the period in question here. While the State's evidence demonstrates the difficulties of determining a best estimate, the State's evidence ultimately does not support the State's use of the AWP.

The regulations clearly required that the State use its best estimate of the amount generally and currently paid. The regulations contemplated an effort by the State to determine this amount in some reasonable manner which could be documented. As this Board said in Oklahoma Dept. of Human Services, DAB No. 1271 (1991), p. 8, developing a "best estimate" of an EAC clearly requires at least some minimal assessment and determination of actual drug costing practices. Moreover, the State was subject to the general requirement in section 1902(a)(30)(A) that its payment methods be consistent with economy. In spite of this obligation, the State had absolutely no data to support use of the AWP. See Tr., pp. 63, 91. What the State's evidence did show is as follows.

The unrebutted testimony presented by the State at the hearing shows that the inappropriateness of using the AWP was not as clear from the State's viewpoint in the mid-1980's, as HCFA asserted it should be. Other states were using the AWP, and the AWP compendia were readily available, with weekly updates which could be loaded onto the State's computerized claims processing system. Tr., pp. 22, 49. The OIG report was not based on a valid statistical sample, and thus did not provide a reliable basis for determining how much the AWP was being discounted in Arkansas. Tr., pp. 49-50, 65.

The testimony further shows that the State encountered administrative difficulties in the process of contracting for a reliable survey and obtaining and evaluating the survey results. The invitation for bid had to be approved by HCFA, and the State had to follow its contracting procedures. Tr., p. 90. Delays were caused through the need to obtain information from the State's fiscal agent. Tr., pp. 24-25, 66. Moreover, the State had to rely on the pharmacists to respond to the survey. Tr., p. 24. The task of analyzing the data was apparently enormous, but Myers and Stauffer nonetheless completed the survey in less time than it took for similar surveys in other states. Tr., pp. 146-148.

The testimony also shows that the question of determining what discount percentage should be applied is not as simple as HCFA's arguments suggested. The amount of the discount given varies considerably (for example, chain pharmacies might obtain a larger discount than independent pharmacies). Tr., pp. 123, 152; HCFA Ex. B, Appendix, p. A-67. This raises an issue of how a state can set a discount which will ensure accessibility to services for Medicaid recipients and avoid legal battles over its reimbursement to providers. Tr., pp. 70-71. This was a legitimate concern for the State since a survey by the Arkansas College of Pharmacy had shown that, if the State were to set the reimbursement level too low, many pharmacists would drop out of the Medicaid program. Tr., p. 125; see also Tr., p. 71. Also, undisputed testimony shows that the "discounts" which the wholesalers were giving to the providers were not all cash discounts. Rather, in some instances the wholesalers were simply shifting costs which had previously been included in the drug prices to appear as a separate charge on the sales invoices. These costs included charges for items or services such as labels, bottles, and computer ordering services. Tr., pp. 117-121.

This evidence is an insufficient basis for the State to prevail here, however. First, as discussed above, the State did not have any data to support use of the AWP, as required. Second, while the testimony shows that the State also did not have the data to support a determination of the exact amount of the discounted prices being paid in Arkansas, the evidence shows that the State could not reasonably think that the full amount of the AWP was being paid generally.[5] The OIG audit certainly was reliable at least in concluding that the AWP was not being paid. The State Director acknowledged that he knew of the OIG audit in 1986 and was on notice through it of the discrepancy between AWP and the actual price paid. Tr., p. 56. The Director of the Division of Economic and Medical Services acknowledged that, based on the OIG audit, HCFA had encouraged the State to look at setting some rate of reimbursement less than AWP. Tr., p. 64.

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[5] Indeed, even the Arkansas Pharmacy Association representative said that nearly all pharmacies were receiving at least a 2% cash discount. Tr., p. 139.

Moreover, the State's explanations of its delay in obtaining reliable data do not justify the initial delay caused through the State proposing in 1988 a plan amendment specifying AWP, nor do they justify the full time period it took to obtain and act on the survey results. One State witness speculated that the State did not act sooner to commission a survey because HCFA was considering a new regulation discounting AWP by 10% and because a lawsuit had been filed by pharmacists who challenged HCFA's position. Tr., pp. 101-102. The record shows, however, that he was referring to the regulatory process which was concluded in 1987 and that the lawsuit was concluded in 1985. See, e.g., HCFA post-hearing brief, attachment. Thus, this does not explain why the State acted in early 1988 to propose a plan amendment specifying AWP, rather than to obtain reliable data on the prices generally and currently paid.

The record shows that the State was not justified in waiting to begin the process of contracting for a survey until after the State received formal disapproval of the plan amendment specifying AWP, in September 1988. The State's own letter sent to HCFA in June 1988 shows that the State was aware of the need for a survey at least as of that date and had assured HCFA it would act expeditiously to commission a survey. HCFA Ex. G, p. 5. The State's testimony about the need to follow contracting procedures was vague and neither specifically nor fully accounts for the three months between the June letter and the time the IFB was issued in September. Tr., p. 90. Moreover, we do not see how the State could have reasonably thought that HCFA might approve the AWP as EAC, given HCFA's April response and the history of HCFA's position on AWP.

The State also did not provide any explanation of why it took as long as it did after receiving the proposals to actually award the contract. The witness from Myers and Stauffer said that they predicted a report date of April 1989 based on an assumption that the award date would be only two weeks or so after they mailed the IFB back, but, instead, a little over a month elapsed. Tr., pp. 144-145. Like this delay, some of the delays once the contract was awarded, such as obtaining needed computer lists from the fiscal agent, would appear to be ultimately the State's responsibility. See Tr., pp. 24-25, 145. While these delays were not lengthy, they contributed to the State's failure to meet the deadline HCFA announced in its March 31, 1989 letter.

Finally, we conclude that the State could not reasonably have relied on the mere fact that it informed HCFA about the delays in obtaining the results of the survey as a basis for thinking that HCFA would extend the deadline announced in HCFA's March 31, 1989 letter. The State did not allege that HCFA had specifically agreed to extend the deadline. See Tr., pp. 51-52, 68. At most, the HCFA letter can be viewed as a conditional agreement to waive a disallowance. The State's failure to meet the condition in the letter by submitting a plan amendment based on the survey by the end of the quarter specified means that the State could not reasonably expect HCFA to refrain from a disallowance solely based on HCFA's silence. While State officials indicated that they may not have understood that payments as of April 1, 1989 would be disallowed if the State did not act by the date specified in the letter, their understanding is irrelevant; the March 31, 1989 letter gave clear notice of HCFA's intention.

In sum, we conclude that the State could not reasonably consider the AWP to be its "best estimate of the amount generally and currently paid;" that the State had constructive notice in 1987 that it needed data to support such an estimate; and that the State actually knew that a survey was needed at least by June 1988. We further conclude that HCFA was reasonable in setting a deadline for the State and in imposing a disallowance when the State failed to meet that deadline.

On the other hand, the record establishes that, in determining the disallowance amount, HCFA applied the AWP minus 10.5%, without considering the other changes in the reimbursement method HCFA agreed to. If the State had implemented its new reimbursement methods so they were effective during the disallowance period (as HCFA said the State should have), the amount the State would have paid would have differed from the amount the State did pay (using AWP) by an amount less than the disallowance amount HCFA calculated. The increase in the dispensing fee would also have been reflected in the State's claims, since this was part of the amendment agreed to. See State Ex. G.

We think that HCFA should reconsider its position on how to calculate the disallowance amount, in light of the testimony presented at the hearing and the other considerations we outline below.

HCFA indicated that it could not approve the new State plan provision retroactive to April 1, 1989 because the State had not implemented the provision until August 1,

1989. HCFA thus thought that it was precluded from using any dispensing fee other than the $4.01 fee specified in the existing State plan.

While certain state plan provisions may not be effective until implemented, regulations which HCFA published in 1988 permit a plan amendment such as this one to be effective on "a date requested by the State if HCFA approves it." 42 C.F.R. 430.20(b)(2) (1988). HCFA's own witness said that HCFA had expected the State to apply an amendment based on the survey back to April 1, 1989, by retroactively adjusting the provider payments. Tr., p. 183. The State's rationale for not doing so was that it had to give timely notice to the providers. See Tr., p. 67. If HCFA is correct that the payments (at least for FFP purposes) could be adjusted retroactively, then we see no reason for denying the State's request for an April 1, 1989 effective date for the plan amendment.

Even if HCFA would not grant this approval, however, it is not clear why HCFA applied part of the new methodology, but not all of it. The regulations on which HCFA relied for the disallowance establish aggregate upper limits on what the State can pay. The regulations use as that aggregate upper limit the lower of EAC "plus reasonable dispensing fees" or usual and customary charges. Although the State may have actually paid only $4.01 as a dispensing fee, the State's survey (which as HCFA pointed out was based on 1988 costs) establishes that the amount of a reasonable dispensing fee for this period was the higher figure HCFA ultimately agreed to.

Moreover, HCFA viewed the term "cost" in the existing plan as "ingredient cost," entirely separate from the dispensing fee. The plan merely says "cost," however, and the State's testimony showed that the wholesalers had been including as drug costs some items that more properly should have been considered part of the dispensing fee. See Tr., pp. 49-50. The State's testimony shows that, if the State had not increased the dispensing fee at the same time as discounting from the AWP, the State would have had to discount by a lesser percentage than 10.5 in order to assure access to services, particularly for recipients in rural areas. As the State pointed out, it must not only consider efficiency and economy in setting reimbursement rates in accordance with section 1902(a)(30)(A) of the Act, but must also consider quality of care.

HCFA's position was essentially that the State was required under the regulations to have implemented a new reimbursement system at least by the beginning of the disallowance period (April 1, 1989).[6] Thus, we conclude that HCFA should consider determining the disallowance amount by calculating the difference between what the State did pay and what the State would have paid if it had implemented the new system by April 1, 1989 (including application of the usual and customary charge limit).

Conclusion

We uphold the disallowance in principle, but remand to HCFA to reconsider how to calculate the disallowance amount. If the State disagrees with HCFA's recalculations, it may return to the Board on that limited issue, within 30 days after receiving notice of HCFA's recalculations.

Donald F. Garrett

Norval D. (John) Settle

Judith A. Ballard
Presiding Board Member

[6] Thus, this case is distinguishable from the situation where a state is making an optional change in its reimbursement system in order to enhance federal funding and seeks to make that change retroactive, without following plan amendment procedures.